DLH McCloskey ↓
Population Con
WHO
depo-provera

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Hon. Paul N. McCloskey, Jr.
Congress of the United States
House of Representatives
Washington, D.C. 20515

Dear Pete:

I am certainly very pleased with the position that you have been taking with respect to the continued support of the WHO program in human reproduction. I would concur with everything you said about the unique place of WHO in dealing with this global problem. It has I believe done very well in striking an effective balance between the need for early substantive progress in research, on the one hand, and the development of indigenous capabilities throughout the world on the other. It is also certainly true that the requested levels of expenditure are pitifully small in relation to the challenge; but this is hardly an argument against sustaining the program at at least this minimum level.

Having said all that, I would still have to enlarge that the problem of effective contraception cannot be considered in isolation. In fact, one of the most serious obstacles to efforts to develop, and perhaps to the rational deployment of, new agents is the concern about side effects, especially cancer, which I am sure will attend every agent that has such a profound effect on human physiology as to be a reliable block to a central biological process. The incipient wreckage of the long-term WHO-supported field trials of depo-provera, which are a nearly certain consequence of the FDA's position on the further development of this substance as a therapeutic agent, in the United States, illustrate what I mean. The prospect of such a scare should no longer be regarded as a potential and unlikely accident but as a virtually certain accompaniment to efforts to introduce any new agents. It is surely obvious that had the present climate prevailed 15 years ago we would not even be able to use the existing oral contraceptives.

Given the FDA's mandate to assure the perfect safety of the American population at whatever cost, it is hard to see any administrative procedures that could ameliorate this situation. I think it does mean that we should be more careful to anticipate the

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CC: H Cordova

magnitude of this overhanging threat at a very early stage of the R&D on newly introduced substances; which is to say that there really is no way to draw a line, between research on preventive measures in cancer, from important applications in human reproduction. What has been mainly lacking on the cancer side, especially at the end of the spectrum that has to do with the ground work for regulatory policy, is any inquiry into mechanism. After all, according to the law, it is sufficient to introduce an agent into an animal and demonstrate a statistical increase in tumors and that case is won.

I certainly do not expect these remarks to influence your very good efforts in the present context, but I thought they might be helpful in your larger consideration of the problems and opportunities for progress in this field.

I hope you will forgive me for being so tardy about responding to your earlier communications but they came at a time when I was simply overwhelmed by other events; and I am glad now to be able to get back into dialogue with you.

Yours sincerely,

Joshua Lederberg,
Professor and Chairman
Dept. of Genetics

P.S. I have had the opportunity to see a good bit of the work of WHO at fairly close hand; but I would be really interested to see the Helman committee report that you mention in your letter to Chairman Long.

JL/gel